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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,211	01/30/2002	Klaus Schumann	3868-0103P	9968

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,211	SCHUMANN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/30/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 07/26/2004.

Claims 11-14 are included in the prosecution.

Applicants' IDS, filed 01/30/2002 have been considered. A copy of the initialized USPTO form 1449 is attached to hereby.

Claim Rejections - 35 USC § 103

1. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,115,913 ('913) in view of WO 96/34633 ('633).

Claim 11 recites a method of preventing pressure-sensitive adhesive (PSA) from leaking out in cold flow during storage of PSA-substrate that sealed in a bag to protect against loss of active substance, the substrate comprising backing, matrix of PSA or provided with PSA layer on its application surface, the method comprising the step of providing a carrier layer on the PSA made of two sections that are overlapping. One of the carrier layer sections is wider than the other by an amount of overlap (claim 12). One of the carrier layer sections is wider than half the width dimension of an undivided carrier layer by the amount of half the overlap (claim 13); and the region of the overlap is positioned centrally or eccentrically (claim 14).

US '913 teaches a method for increasing the storage stability and protection from cold flow of PSA in a transdermal device, and protection of volatile components from evaporation. The transdermal device is packed and sealed in a bag comprising substrate sections that are PSA or rendered PSA on their surfaces and protected by

support layer on one side and carrier layer on the other side (abstract; col.1, lines 1-47). The reference teaches method for prevention of cold flow by providing means to prevent migration of PSA by manipulating the carrier layer.

The difference between the present invention and the cited reference is the structure of the carrier layer that prevents the migration of the PSA.

WO '633 teaches a dressing set (substrate sections) that keeps the active agent in a reservoir at a constant level for a prolonged storage time (abstract; page 2, last paragraph). The dressing set comprising a backing; a reservoir containing at least one pharmaceutically active substance; a pressure sensitive adhesive surface layer on one of the surfaces of the backing; and more than one peel stripes (abstract). The peel stripes extend beyond the edges of the dressing and are overlapping (page 4, paragraph 3, figure 2). It is evident from figure 2 that both carrier layer sections are overlapping in the center of the dressing (claim 14). Figure 2 also shows that one carrier section is wider than the other by the amount of the overlap (claim 12). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 13). In any events, applicants are not

claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a transdermal device having PSA layer sealed in a bag for prolonged storage and prevention of cold flow as disclosed by US '913, and replace the carrier layer that have been manipulated to protect against migration of PSA by the carrier layer having two overlapping sections disclosed by WO '633, motivated by the desire of WO '633 to keep the active agent in the reservoir at a constant level for a prolonged storage time (as also desired by applicants), with reasonable expectation to achieve a transdermal device comprising PSA layer that is sealed in bag and having carrier layer with two overlapping sections that has increased stability of the drugs in the patch and prevent PSA leak from the device during storage.

Response to Arguments

2. Applicant's arguments filed 07/26/2004 have been fully considered but they are not persuasive.

Applicants traverse the above rejection by arguing that the problem to be solved by the present invention was to prevent leakage of pressure-sensitive adhesive (due to cold flow) from pressure-sensitive adhesive substrate sections by configuring this carrier layer with two overlapping sections (having an incision), and by positioning the overlap on the pressure-sensitive adhesive (PSA), while US '913 does not teach how to prevent leakage of PSA during storage, but it rather teaches how to prevent agglutination if such

leakage will occur during storage. US '913 does not concern adhesive substrates which are covered on their adhesive surface. It might also be said that US '913 teaches away from the present invention, as it teaches that leakage caused by cold flow cannot be prevented as such, and that the skilled person should think about methods to prevent the PSA that has escaped from the substrate sections from adhering the substrate sections of the carrier layer to the inner wall of the packing.

As regards WO '633 does not teach to position the overlap of the carrier layer on a pressure-sensitive adhesive substrate section. The overlap of the peel strips shown in Fig. 2 is positioned on top of a non- adhesive, active substance-containing compress or swab. Furthermore, like US '913, WO '933 fails to address the problem of preventing the leakage of PSA due to cold flow during prolonged storage. Instead, WO '633 is concerned with preventing the migration (by diffusion) of active compound out of the compress-type reservoir into the backing layer to which this reservoir is attached. The phenomenon of leakage of active substance is not comparable to the phenomenon of leakage of PSA due to cold flow.

Therefore, the skilled person desiring to "keep the active agent in the reservoir" could not have been motivated by WO '633 to replace the carrier layer of US '913 by the peel strips of WO '633, as the possible function of these strips with respect to preventing loss of active substance or preventing leakage of PSA caused by cold flow was not discussed in WO '633. The only thing the skilled person could have learned from WO '633 with respect to preventing loss of active substance during storage is that when using a non-occlusive backing layer, it may be advantageous to interpose an

occlusive foil between the active substance-containing reservoir and said backing layer, in order to prevent diffusion of active substances from the reservoir into and through said backing layer. In conclusion, we take the position that the skilled person would have not have considered combining US '913 and WO '633 as suggested by the Examiner, and such combination would not have resulted in the invention as presently claimed.

3. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The primary reference teaches clearly protection of pressure sensitive adhesive layer by packaging in a bag and by the support layer that project over the PSA layer (col.1, lines 6-45). What applicants did was preventing the PSA layer from leaking, and not preventing the cold flow from happening. Applicants achieved their goal by packaging the device comprising PSA layer, and covering the PSA layer, and that what the prior art teaches. The secondary reference teaches the coverage of the adhesive layer by two overlapping sections for protecting the contents of the device. Thus, it is obvious to combine the two references. The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the

reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In response to applicant's argument that US '913 teaches away from the present invention, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, US '913 is concerning with protecting the PSA by packaging and other layers that cover the PSA.

Regarding WO '633, Applicants admit that the structure of the dressing disclosed by WO '633 is the same as the structure claimed by applicant except for the PSA surface of the reservoir is not the surface that is covered by the overlapping sections. However, the reference disclosed a PSA layer on the reservoir layer, and that is exactly how applicants rendered the matrix PSA as per present disclosure at page 3, forth paragraph. The claim recites either the matrix is made of PSA or rendered PSA. Further, it is expected for the dressing of WO '633 that has the same structure of overlapping carrier and reservoir rendered adhesive to perform the same function as

desired by applicants, i.e. avoidance of the leakage of the PSA. Rearrangement of the layers of the device to make the adhesive surface covered by the overlapping layers does not make the instant method patentable because the function of the device have not been modified, and the protection of the adhesive is achieved, as taught by the prior art. In addition, WO '633 is relied upon for teaching the protection of the contents of the device using the overlapping sections.

In response to applicant's argument that the combination of the references would not lead to the present invention, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation would arise from the desire of WO '633 to keep the contents of the device in the reservoir at a constant level for a prolonged storage time (as also desired by applicants), with reasonable expectation to achieve a transdermal device comprising PSA layer that is sealed in bag and having carrier layer with two overlapping sections that has increased stability of the drugs in the patch and prevent PSA leak from the device during storage. In response to applicant's argument that the only thing the skilled person could have learned from combination of US '913 and WO '633 is to use a non-occlusive backing layer during storage, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art

cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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